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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,645	08/05/2003	Mauricio Rojas	60068.0002US01	7190

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/634,645

Applicant(s)

ROJAS ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 17-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/1/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 11 November 2004, is acknowledged. Applicants elect, without traverse, Invention I, claims 1-16, drawn to fusion proteins, classified in class 424, subclass 192.1.

Claims 1-88 are pending. Claims 17-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 1-16 are under consideration.

### Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-9 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,432,680 in view of WO03/002598.

Mauricio Rojas is listed as an inventor on both U.S. Patent No. 6,432,680 and the instant application.

The instant claims are drawn to an isolated fusion protein comprising a membrane-translocating sequence comprising at least eight-12 consecutive residues of SEQ ID NO:1 (Ala-Ala-Val-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro) and an I $\kappa$ B protein.

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Claims 1-12 of U.S. Pat. No. 6,432,680 are drawn to an isolated fusion protein comprising a membrane-translocating sequence comprising at least 8-12 consecutive residues of SEQ ID NO:1 (Ala-Ala-Val-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro) and an target peptide or a target polypeptide.

WO03/002598 teaches fusion proteins comprising a membrane-translocating sequence and further comprising an I $\kappa$ B protein for pharmaceutical/therapeutic use (page 23, lines 6-9).

Therefore, since claims 1-12 of U.S. Pat. No. 6,432,680 teach the specific construct of a membrane-translocating sequence, SEQ ID NO:1, of the present application with any target peptide/polypeptide and WO 03/002598 teach a fusion protein comprising a membrane-translocating sequence with a particular target polypeptide, i.e., I $\kappa$ B protein of the instant claims, the conflicting claims, while not identical, are not patentably distinct from each other in light of the cited references.

### **Claim Rejections - 35 USC § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al (U.S. Pat. No. 6,248,558) in view of Crisanti (WO 03/002598).

The instant claims 1-9 are drawn to an isolated fusion protein comprising a membrane-translocating sequence comprising at least eight-12 consecutive residues of SEQ ID NO:1 (Ala-Ala-Val-Leu-Pro-Val-Leu-Leu-Ala-Ala-Pro) and an I $\kappa$ B protein.

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Lin et al teach an isolated fusion protein comprising a membrane-translocating sequence comprising at least eight-12 consecutive residues of SEQ ID NO:1 (Ala-Ala-Val-Leu-Pro-Val-Leu-Leui-Ala-Ala-Pro) and any target peptide or polypeptide, i.e., NFκB (Abstract; col. 2, lines 65-67; 4, col 4, line 49 to col 5, line 27).

However, Lin et al do not specifically teach an isolated fusion protein comprising a membrane-translocating sequence comprising at least eight-12 consecutive residues of SEQ ID NO:1 (Ala-Ala-Val-Leu-Pro-Val-Leu-Leui-Ala-Ala-Pro) and an IκB protein.

Crisanti (WO03/002598) does teach fusion proteins comprising a membrane-translocating sequence and further comprising an IκB protein for pharmaceutical/therapeutic use (page 23, lines 6-9).

Claims 10-16 are likewise drawn to the fusion protein of claims 1-9 but with addition components such as tag amino acid sequences, antibody, and pharmaceutically acceptable carrier. Lin et al teach these additional components (col 7, line 1 to col. 21, line 8).

Thus, it would have been obvious to a person having ordinary skill in the art to utilize the fusion proteins comprising the membrane-translocating sequence taught by Lin et al comprising the IκB protein for pharmaceutical/therapeutic use as taught by Crisanti.

### **Conclusion**

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

February 7, 2005